

CLAIMS

1. A reagent for the determination of the clotting time of a blood
5 sample from a patient receiving heparin treatment, wherein the clotting time is
used to determine the effectiveness of the treatment, comprising tissue factor
and a sulfatide in relative amounts sufficient to determine the effectiveness of
heparin treatment in relation to clotting time in a sample from a patient receiving
sufficient heparin to have a blood heparin level of up to about 6 U/mL.

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2. The reagent of claim 1, wherein said reagent is anhydrous.

3. The reagent of claim 1, wherein said tissue factor is present in
sufficient quantity in said reagent so that when an effective amount of said
15 reagent is added to a blood sample to clot the sample, the sample comprises
between about 50 and about 1000 ng/mL tissue factor.

4. The reagent of claim 3, wherein a sample after contact with an
effective amount of said reagent comprises about 100 ng/mL tissue factor.

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5. The reagent of claim 1, wherein said sulfatide is present in
sufficient quantity in said reagent so that when an effective amount of said
reagent is added to a blood sample to clot the sample, the sample comprises

between about 1 and about 4 mg/mL sulfatide.

6. The reagent of claim 5, wherein the sample after contact with an effective amount of said reagent comprises about 3 mg/mL sulfatide.

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7. The reagent of claim 1, wherein said reagent further comprises a buffer and a stabilizer.

8. A test cartridge for the determination of the clotting time of a blood sample from a patient receiving heparin treatment, wherein the clotting time is used to determine the effectiveness of the treatment, comprising:

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a housing containing an inlet port, a chamber unit, and an exit port, said inlet port, chamber unit, and exit port being present in a continuous capillary pathway; and

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a reagent in said capillary pathway comprising tissue factor and a sulfatide

9. The test cartridge according to claim 8, wherein said tissue factor is recombinant human tissue factor and said sulfatide is bovine brain sulfatide.

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10. The test cartridge of claim 8, wherein said tissue factor is present in sufficient quantity in said reagent so that when an effective amount of said

reagent is contacted with a blood sample to clot the sample, the sample comprises between about 50 and about 1000 ng/mL tissue factor

11. The test cartridge of claim 10, wherein a sample after contact with
5 an effective amount of said reagent comprises about 100 ng/mL tissue factor.

12. The test cartridge of claim 8, wherein said sulfatide is present in
sufficient quantity in said reagent so that when an effective amount of said
reagent is contacted with a blood sample to clot the sample, the sample
10 comprises between about 1 and about 4 mg/mL sulfatide.

13. The test cartridge of claim 12, wherein the sample after contact
with an effective amount of said reagent comprises about 3 mg/mL sulfatide.

14. The test cartridge according to claim 8, wherein said reagent
15 further comprises a buffer and a stabilizer.

15. A test cartridge for the determination of the clotting time of a blood
sample from a patient receiving heparin treatment, wherein the clotting time is
20 used to determine the effectiveness of the treatment, comprising:

a housing containing an inlet port, a chamber unit, an exit port, a first
capillary unit for independently pumping a liquid from said inlet port to said

chamber unit, and a second capillary unit positioned between and operatively connected to said chamber unit and said exit port for independently pumping a liquid from said chamber unit to said exit port; wherein said inlet port, first capillary unit, chamber unit, second capillary unit, and exit port are present in a continuous capillary pathway; and

a reagent in said capillary pathway comprising tissue factor and a sulfatide.

16. A reagent for the determination of the effectiveness of heparin treatment in a patient receiving same, comprising tissue factor and at least one co-factor selected from the group consisting of a phosphatide and a sulfatide, wherein when a sufficient quantity of said reagent is contacted with a blood sample from a patient, clotting time can be used to determine to the effectiveness of heparin therapy to the patient.

17. The reagent of claim 16, wherein said reagent is anhydrous.

18. The reagent of claim 16, wherein said tissue factor is present in sufficient quantity in said reagent so that when an effective amount of said reagent is added to a blood sample to clot the sample, the sample comprises between about 50 and about 1000 ng/mL tissue factor.

19. The reagent of claim 18, wherein the sample after contact with an effective amount of said reagent comprises about 100 ng/mL tissue factor.

5 20. The reagent of claim 16, wherein said at least one co-factor selected from the group consisting of a phosphatide and a sulfatide is present in sufficient quantity in said reagent so that when an effective amount of said reagent is added to a blood sample to clot the sample, the sample comprises a combined total of said phosphatide and said sulfatide combined between about 1 and about 4 mg/mL.

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21. The reagent of claim 20, wherein the sample after contact with an effective amount of said reagent comprises a combined total of said phosphatide and said sulfatide of about 3 mg/mL.

15 22. The reagent of claim 16, wherein said reagent further comprises a buffer and a stabilizer.

23. A test cartridge for the determination of the effectiveness of heparin treatment in a patient receiving same, comprising:

20 a housing containing an inlet port, a chamber unit, and an exit port, said inlet port, chamber unit, and exit port being present in a continuous capillary pathway; and a reagent in said capillary pathway comprising tissue factor and at

least one co-factor selected from the group consisting of a phosphatide and a sulfatide.

24. The test cartridge according to claim 23, wherein said tissue factor
5 is recombinant human tissue factor, said sulfatide is bovine brain sulfatide, and
said phosphatide is phosphatidyl choline.

25. The test cartridge of claim 23, wherein said tissue factor is present
in sufficient quantity in said reagent so that when an effective amount of said
10 reagent is contacted with a blood sample to clot the sample, the sample
comprises between about 50 and about 1000 ng/mL tissue factor.

26. The test cartridge of claim 25, wherein the sample after contact
with an effective amount of said reagent comprises about 100 ng/mL tissue
15 factor.

27. The test cartridge of claim 23, wherein at least one co-factor from
said group consisting of a phosphatide and a sulfatide is present in sufficient
quantity in said reagent so that when an effective amount of said reagent is
20 contacted with a blood sample to clot the sample, the sample comprises a
combined total of said phosphatide and said sulfatide between about 1 and
about 4 mg/mL.

28. The test cartridge of claim 27, wherein the sample after contact with an effective amount of said reagent comprises a combined total of said phosphatide and said sulfatide of about 3 mg/mL.

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29. The test cartridge according to claim 27, wherein said reagent further comprises a buffer and a stabilizer.

30. A reagent for use in determining the effectiveness of heparin treatment in patients receiving same, comprising a sulfatide and a phosphatide, wherein said sulfatide and said phosphatide are present in a ratio by weight of said phosphatide to said sulfatide of about 1/3 to about 3/1, and said reagent can determine heparin treatment effectiveness in patients receiving sufficient heparin to have blood heparin levels between about 0 U/mL and about 6 U/mL.

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31. The reagent of claim 30, further comprising tissue factor.

32. A test cartridge for the determination of the effectiveness of heparin treatment in patients receiving same, comprising:

20 a housing containing an inlet port, a chamber unit, an exit port, a first capillary unit for independently pumping a liquid from said inlet port to said chamber unit, and a second capillary unit positioned between and operatively

connected to said chamber unit and said exit port for independently pumping a liquid from said chamber unit to said exit port; wherein said inlet port, first capillary unit, chamber unit, second capillary unit, and exit port are present in a continuous capillary pathway; and

5 a reagent in said capillary pathway comprising tissue factor and a phosphatide.

33. A reagent for use in determining the effectiveness of heparin treatment in patients receiving sufficient heparin to have a blood heparin level
10 between about 0 U/mL and about 6 U/mL, comprising tissue factor and a cofactor, wherein, when an effective amount of said reagent is contacted with a blood sample from a patient having a blood heparin level between about 0 U/mL and about 6 U/mL, a predetermined degree of clotting is reached in less than about 300 seconds.

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34. The reagent of claim 33, wherein said cofactor comprises at least one of the group consisting of a sulfatide and a phosphatide.